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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/533,798 03/24/2000 Miles William Carroll 078883/0120 2448

22428 7590 03/19/2003

FOLEY AND LARDNER
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3000 K STREET NW
WASHINGTON, DC 20007

EXAMINER

SCHEINER, LAURIE A 13

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 03/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/533,798

Applicant(s)
Carroll et al.

Examiner
Laurie Scheiner

Art Unit
1648



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (e). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jan 2, 2003
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6, 8-16, 18-34, and 41-45 is/are pending in the application.
- 4a) Of the above, claim(s) 1-4, 6, 8, 13, 15, 18-34, and 41-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-12, 14, and 16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 5 6) ☐ Other:

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Claims 1-4, 6, 8-16, 18-34 and 41-45 are pending in this application

Applicant's election of Group III (claims 9-12, 14 and 16) in Paper No. 12 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 1-4, 6, 8, 13, 15, 18-34 and 41-45 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14 is vague and indefinite due to the recitation of "peptide epitope of 5T4 antigen and wherein said antigen induces a CTL response." One cannot determine which epitope is intended; also, it is unclear as whether the CTL response results from the undefined epitope or the antigen.

Claims 12 and 16 are indefinite since they fail to set forth clear discrete process steps. That is, the claims do not set forth any steps involved in the method/process.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one

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skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *In re Rasmussen*, 650 F.2d 1212, 211 U.S.P.Q. 323 (C.C.P.A. 1981). *In re Wertheim*, 541 F.2d 257, 191 U.S.P.Q. 90 (C.C.P.A. 1976). Amended claim 14 is drawn toward a method employing a "peptide epitope". The written description requirement under Section 112, first paragraph, sets forth that the claimed subject matter must be supported by an adequate written description that is sufficient to enable anyone skilled in the art to make and use the invention. The courts have concluded that the specification must demonstrate that the inventor(s) had possession of the claimed invention as of the filing date relied upon. Although the claimed subject matter need not be described identically, the disclosure relied upon must convey to those skilled in the art that applicants had invented the subject matter claimed. *In re Wilder, et al.*, 222 U.S.P.Q. 369 (C.A.F.C. 1984). *In re Wertheim, et al.*, 191 U.S.P.Q. 90 (C.C.P.A. 1976). *In re Driscoll*, 195 U.S.P.Q. 434 (C.C.P.A. 1977). *Utter v. Hiraga*, 6 U.S.P.Q.2d 1709 (C.A.F.C. 1988). *University of California v. Eli Lilly*, 119 F.3d 1559, 43 U.S.P.Q.2d 1398 (Fed. Cir. 1997). *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 U.S.P.Q.2d 1016-1031 (C.A.F.C. 1991). *Fiers v. Sugano*, 25 U.S.P.Q.2d 1601-1607 (C.A.F.C. 1993). *In re Bell*, 26 U.S.P.Q.2d 1529-1532 (C.A.F.C. 1993). The significance of conception and reduction to practice was further addressed by the court in *Fiers v. Sugano* where it was emphasized that "[c]onception is a question of law, reviewed *de novo* on appeal, and if inventor is unable to envision detailed chemical structure of DNA sequence coding for specific protein, as well as method of obtaining it, then conception is not achieved until reduction to practice has occurred, that is, until after gene has been isolated; thus, regardless of complexity or simplicity of method of isolation employed, conception of DNA sequence, like conception of any chemical substance, requires definition of that substance other than by its functional utility."

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Applicant's disclosure fails to provide adequate written support for the invention as claimed. That is, applicant's claim encompasses a method of employing a "peptide epitope" of an antigen; the epitope is undefined outside its generic meaning. Rather, the specification provides a description of the 5T4 antigen and use thereof. As such, the disclosure fails to provide an adequate written description for subject matter as claimed.

The examiner contends that one of skill cannot reproduce that which has not been described. That is, it is evident that applicants were not in possession of that which is claimed at the time of the invention. It is well settled that the claimed subject matter need not be supported by an explicit, word for word recitation, but something more than a suggestion is needed to satisfy the requirement for an adequate written description. As set forth in Lockwood v. American Airlines Inc., 107 F.3d 1565, 1571-1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997):

It is the disclosures of the applications that count. Entitlement to a filing date extends only to that which is disclosed. While the meaning of terms, phrases, or diagrams in a disclosure is to be explained or interpreted from the vantage point of one skilled in the art, all the limitations must appear in the specification.

Rather, a[n]... application itself must describe an invention, and do so in sufficient detail that one skilled in the art can clearly conclude that the inventor invented the claimed invention as of the filing date sought... [A]ll that is necessary to satisfy the description requirement is to show that one is "in possession" of the invention...

One shows that one is "in possession" of the invention by describing the invention, with all its claimed limitations, not that which makes it obvious. . .

Although the exact terms need not be used in haec verba, . . . the specification must contain an equivalent description of the claimed subject matter. [Citations omitted]

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 9-12, 14 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Stern et al. (US Patent 5,869,053).

Stern et al. clearly teach a vaccine composition comprising a 5T4 antigen as the immunizing agent as claimed. Please see at column 3, wherein the compositions comprise the 5T4 antigen together with a carrier or diluent, and where the antigen is to be used as a vaccine, the carrier will be a parenterally acceptable liquid carrier. Please also see the claims wherein a 5T4 antigen fragment is capable of forming a complex with antibodies to 5T4 antigen, and the specification at column 2 (last paragraph) to column 3 teach^{es} that the 5T4 glycoprotein and fragments thereof are useful in the production of vaccines.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laurie Scheiner, whose telephone number is (703) 308-1122. Due to a flexible work schedule, the examiner's hours typically vary each day. However, the examiner can normally be reached Monday thru Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

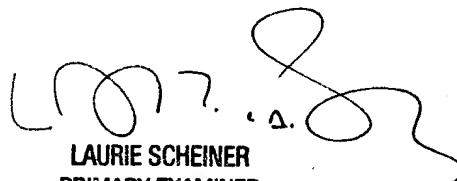
Correspondence related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official

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Gazette, 1096 OG 30 (November 15, 1989). Official communications should be directed toward one of the following Group 1600 fax numbers: (703) 308-4242, (703) 305-3014, (703) 872-9306 or (703) 872-9307. Informal communications may be submitted directly to the Examiner through the following fax number: (703) 746-5226.



Laurie Scheiner/LAS
March 4, 2003



LAURIE SCHEINER
PRIMARY EXAMINER